SESLHD PROCEDURE COVER SHEET

NAME OF DOCUMENT	Sterilisation: Control of nonconforming Reusable Medical Devices (RMD) and Recall of RMDs
TYPE OF DOCUMENT	Procedure
DOCUMENT NUMBER	SESLHDPR/504
DATE OF PUBLICATION	October 2019
RISK RATING	Low
LEVEL OF EVIDENCE	National Safety Quality Health Service Standards: Standard 3 - Preventing and Controlling Healthcare Associated Infections Australian/New Zealand Standard AS/NZS 4187:2014
REVIEW DATE	October 2024
FORMER REFERENCE(S)	Nil
EXECUTIVE SPONSOR or EXECUTIVE CLINICAL SPONSOR	Director of Clinical Governance and Medical Services
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KEY TERMS	Reusable Medical Device, non-conforming, recall, sterilisation
SUMMARY	The document outlines the procedure for identifying and controlling nonconforming RMDs, after completion of reprocessing, and the recall of RMDs that have been detected as nonconforming after distribution.

Sterilisation: Control of nonconforming Reusable Medical Devices (RMD) and Recall of RMDs

SESLHDPR/504

1. POLICY STATEMENT

When a nonconforming Reusable Medical Device (RMD) is identified during reprocessing activities, after delivery or use, Health Service Organisations (HSO) will take action appropriate to the type and possible effects of the nonconforming RMD.

2. BACKGROUND

Non-conforming RMDs are those items that do not meet acceptance criteria after the reprocessing activities or an adverse event is associated with the RMD.

3. RESPONSIBILITIES

3.1 Employees will:

- Comply with the requirements of this procedure
- Report non-compliance with this procedure

3.2 Line Managers will:

- Support compliance with this procedure.

3.3 District Managers/ Service Managers will:

- Implement the requirements of the procedure to assure delivery of quality and safe RMDs

3.4 Medical staff will:

Comply with the requirements of the procedure

4. PROCEDURE

4.1 Nonconforming RMDs detected during reprocessing

Examples of nonconforming RMDs that do not meet acceptance criteria for release during reprocessing include:

At completion of cleaning processes	• RMD is visually dirty after completion of cleaning process • Failed routine tests on selected RMDs • Cycle records do not comply with process specification
At completion of inspection	• RMD is non-functional • RMD is damaged soiled or incomplete

At completion of packaging processes	• Inappropriate packaging system is used • Incorrect wrapping method is used • Incorrect closure and incorrectly labelled • Compromised sterile barrier system (SBS)
At completion of sterilising processes	• Cycle records do not confirm achievement of process parameters established during performance qualification (PQ) • External chemical indicator has not changed as per manufacturers specifications • Closure is compromised, SBS is damaged, visible moisture present on the SBS

Correction of nonconformity:

- Record identified nonconformity
- Establish reasons for nonconformity
- Establish actions to be taken as appropriate
- Record actions taken to address the nonconformity.

4.2 Nonconforming RMDs detected after delivery or use

Examples of nonconforming RMDs that do not meet acceptance criteria after delivery or use include:

After delivery	• Incorrect handling and transport • Missing or defective batch label, resulting in the RMD not being able to be identified as having been exposed to the appropriate reprocessing processes • Inappropriate storage • Exposure to moisture and condensation • Exposure to incorrect temperature • Exposure to excessive sunlight or other sources of ultraviolet light
After use	• The processed biological indicator is positive following incubation, if biological indicators are used. • Recall by the sponsor

Correction of nonconformity:

- Recall of a nonconforming RMD as per HSO specific procedures

5. DOCUMENTATION

- Specific HSO Procedures

6. AUDIT

Nil

7. REFERENCES

AS/NZS 4187:2014 Reprocessing of reusable medical devices in health service organisation

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
April 2016	1	SESLHD Sterilisation Resource Group
June 2016	1	To Executive Sponsor for endorsement
July 2016	1	To Clinical and Quality Council for endorsement
July 2016	1	Approved by Clinical and Quality Council
October 2019	2	SESLHD Sterilising Working Party (SSWP) conducted a minor review. Background information updated. Approved by Executive Sponsor. Formatted by Executive Services prior to publishing.